

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re U.S. Patent No. 7,547,700 B2	)	
	)	
Issue Date: June 16, 2009	)	Examiner: David K. O'Dell
	)	
Application No.: 10/518,394	)	Confirmation No.: 8214
	)	
Filing Date: December 17, 2004	)	
	)	
Inventors: Bernard Vacher <i>et al.</i>	)	
	)	
For: ARYL-[4-HALO-	)	
4(HETEROARYLMETHYLAMINO)-	)	
METHYL]-PEPERIDIN-1-YL]-	)	
METHANONE DERIVATIVES, METHODS	)	
FOR PRODUCTION AND USE THEREOF	)	
AS MEDICAMENTS	)	

Box: Petitions

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**PETITION TO THE DIRECTOR UNDER 37 C.F.R. § 1.181 REQUESTING REVIEW OF  
THE DISMISSAL OF PATENTEE'S REQUEST FOR RECONSIDERATION OF  
PATENT TERM ADJUSTMENT - POST GRANT**

In accordance with 37 C.F.R. § 1.181(a)(3), Patentee hereby petitions the Director of the U.S. Patent and Trademark Office ("USPTO") for review of the Decision on the Application for Patent Term Adjustment Post-Grant ("Decision") mailed on December 8, 2009.

Patentee attaches the following documents, for the Director's convenience: (1) Application for Patent Term Adjustment Post-Grant filed July 30, 2009; (2) Federal

Circuit's decision in *Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir. Jan. 7, 2010); (3) the Decision; and (4) USPTO Notice dated January 26, 2010, entitled "Interim Procedure for Patentees to Request a Recalculation of the Patent Term Adjustment to Comply with the Federal Circuit Decision in *Wyeth v. Kappos* Regarding the Overlapping Delay Provision of 35 U.S.C. § 154(b)(2)(A)."

**I. Statement of the Facts**

**A. Patent Term Adjustment in Patentee's Petition Under 37 C.F.R. §1.705(d)**

The USPTO issued U.S. Patent No. 7,547,700 B2 ("the '700 patent") on June 16, 2009. The face of the '700 patent indicates a patent term adjustment of 430 days. On July 30, 2009, Patentee timely filed an Application for Patent Term Adjustment Post-Grant ("Petition"), explaining that the patent term adjustment should be 977 days according to the district court's decision in *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C 2008).

In the Petition, Patentee calculated an initial USPTO delay of 579 days based on the filing date of the instant application and the mailing date of the first Office Action on the merits pursuant to 35 U.S.C. § 154(b)(1)(A)(i), the period of "A delay." This period of A delay tolled on September 19, 2007, the mailing date of the first Office Action. Patentee also calculated in the Petition a subsequent USPTO delay of 547 days based on the filing date of the instant application and the issue date of the resulting patent pursuant to 35 U.S.C. § 154(b)(1)(B)(iii), the period of "B delay." This period of B delay began to toll on December 18, 2007, and ended on June 16, 2009, when the '700 patent issued. From this total USPTO delay of 1,126 days, Patentee subtracted 149

days, due to Applicant delay during prosecution, to arrive at a total patent term adjustment of 977 days stated in the Petition.

Patentee's calculation of the 547 days for the B delay in the initial Petition was based on an application filing date of December 17, 2004. Upon reconsideration, Patentee agrees with the USPTO's calculation of the B delay of 546 days based on the date on which the national stage began, which is December 18, 2004, 30 months from the earliest claimed priority date of June 18, 2002. See Decision at 1. Accordingly, the period of B delay began to toll on December 18, 2007, and ended on June 16, 2009, when the '700 patent issued. Thus, Patentee now believes that the correct patent term adjustment for the '700 patent should be 976 days  $((579+546)-149)$ .

**B. The Court of Appeals for the Federal Circuit Affirmed the District Court's Ruling in *Wyeth***

In a recent decision, the Federal Circuit affirmed the district court's holding. See *Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir. Jan. 7, 2010). Interpreting 35 U.S.C. § 154(b), the Court detected no ambiguity in the statute as to when periods of USPTO delay overlap. As the Court instructed, the period of A delay "begins with a 'failure of the [PTO]' to meet one of the deadlines specified in subparagraphs (i)-(iv) . . . [and] ends when 'the action described . . . is taken.'" *Slip Op.* at 7-8 (citing 35 U.S.C. § 154(b)(1)(A)). In the case of the '700 patent, the period of A delay began on February 17, 2006, the date that is fourteen months from the application's filing date, and ended on September 19, 2007, the mailing date of the first Office Action.

The period of B delay, the Court concluded, "begins when the PTO fails 'to issue a patent within 3 years after the actual filing date of the application in the United States'

. . . [and] ends when ‘the patent is issued.’” *Id.* at 8 (citing 35 U.S.C. § 154(b)(1)(B)). In the case of the ‘700 patent, the period of B delay began on December 18, 2007, the date that is three years from the date on which the national stage of the preceding PCT application commenced, and ended on June 16, 2009, the issue date of the ‘700 patent.

Based on these definitions of A delay and B delay, the court concluded that no overlap between a period of A delay and a period of B delay “happens unless the violations occur at the same time.” *Id.* In other words, “before the three-year mark, no ‘overlap’ can transpire between the A delay and the B delay because the B delay has yet to begin or take any effect.” *Id.* In the case of the ‘700 patent, the initial period of A delay occurred before December 18, 2007. Thus, according to the Federal Circuit’s decision in *Wyeth*, the USPTO’s period of A delay did not overlap its period of B delay.

Under 35 U.S.C. § 2(b)(2)(A), the USPTO has a duty to establish regulations “not inconsistent with the law.” In *Wyeth*, the Court explained the proper construction of the provisions of 35 U.S.C. § 154(b) for determining patent term adjustment. In accordance with *Wyeth*, the period of A delay and the period of B delay in the case of the ‘700 patent should be counted separately, making the patent term adjustment for this patent 976 days, as set forth above.

**C. The USPTO Intends to Readjust Its Calculation of Patent Term Adjustment Based on the Federal Circuit’s *Wyeth* Decision**

Subsequent to the Federal Circuit’s decision in *Wyeth*, the USPTO issued a Notice dated January 26, 2010, entitled “Interim Procedure for Patentees to Request a Recalculation of the Patent Term Adjustment to Comply with the Federal Circuit Decision in *Wyeth v. Kappos* Regarding the Overlapping Delay Provision of 35 U.S.C.

§ 154(b)(2)(A)” (“Notice”). The USPTO recognized the Federal Circuit’s holding in *Wyeth* that “the USPTO’s interpretation of 35 U.S.C. 154(b)(2)(A) was too strict, and that periods of delay overlap under 35 U.S.C. 154(b)(2)(A) only if the periods which measure the amount of adjustment under 154(b)(1) occur on the same calendar day.” Notice at 3. Accordingly, the Notice indicates that the USPTO “is in the process of revising the computer program it uses to calculate patent term adjustment to calculate overlapping days consistent with the Federal Circuit’s interpretation . . . in *Wyeth*.” *Id.* at 4. The USPTO has agreed with the Court’s holding in *Wyeth* and is now taking steps to calculate future patent term adjustments based on this decision. Thus, under the USPTO’s recent policy change, the period of A delay and the period of B delay in the case of the ‘700 patent should be counted separately.

While the USPTO offers a means to patentees for requesting that pre-*Wyeth* patent term adjustments recalculated, this route of correction is only possible if the patentee files such a request within 180 days of the issue date of the patent. See Notice at 1. In the case of the ‘700 patent, filing such a request is not possible because this patent issued on June 16, 2009, while the events of the Federal Circuit’s decision and the USPTO’s change in policy were very recent. Thus, Patentee seeks the Director’s reconsideration of the Decision through this petition under 37 C.F.R. § 1.181.

## II. Points to Be Reviewed

### A. **The Basis for the USPTO's Dismissal of Patentee's Petition Is Contrary to the Federal Circuit's Decision In *Wyeth***

In its Decision, the USPTO used an interpretation of 35 U.S.C. § 154(b)(2)(A) that it now concludes is "too strict," as discussed above. Specifically, the Decision articulates the basis for its decision as follows.

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), *the entire period during which the application was pending* (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), *and not just the period beginning three years after the actual filing date of the application, is the period of delay overlap under 35 U.S.C. 154(b)(2)(A)*. Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment.

Decision at 2. Emphasis added. Applying this rationale, the USPTO reasoned that the "period during which the application was pending before the Office [began] on the date that the national stage commenced. . . , December 18, 2004, and [ended] on the date that the patent issued, June 16, 2009." *Id.* at 3. As such, the USPTO concluded that the 579 day period of A delay overlapped with the 546 day period of B delay and therefore did not count each period of delay separately.

The underlying rationale on which the USPTO based its conclusion in the Decision is inconsistent with the Federal Circuit's holding in *Wyeth*. Whereas the USPTO's rationale suggests that the entire period during which the application was pending, and not just the period beginning three years after the actual filing date of the application, is the period of delay overlap under 35 U.S.C. § 154(b)(2)(A), the Federal

Circuit instructed that the period of B delay begins when the PTO fails to issue a patent within 3 years after the actual filing date of the application in the United States and ends when the patent is issued. Thus, contrary to the USPTO's reasoning in the Decision, the Federal Circuit did not hold that the period of B delay spans the entire period during which the application was pending. Indeed, the Court noted that before the three-year mark, no overlap can transpire between the A delay and the B delay because the B delay has yet to begin.

**B. The Basis for the USPTO's Dismissal of Patentee's Petition Is Contrary to the USPTO's Current Position on *Wyeth***

As discussed above, the USPTO has since announced a change in its policy to calculate future patent term adjustment in a manner consistent with the Federal Circuit's holding in *Wyeth*. To the extent that the rationale underlying the USPTO's dismissal of Patentee's Petition is inconsistent with the Federal Circuit's holding, this Decision is also inconsistent with the USPTO's own current policy on patent term adjustment calculation as provided in the Notice.

**III. Action Requested**

Patentee timely filed the Petition based on the district court's holding in *Wyeth*. Since that Petition and the USPTO Decision that followed, the Federal Circuit has affirmed the District Court's decision and the USPTO has adjusted its own policies regarding the calculation of patent term adjustment to be consistent with the Federal Circuit's holding. As Patentee cannot seek a recalculation of patent term adjustment as provided for under the Notice, Patentee has timely filed this petition under 37 C.F.R. § 1.181.

For the reasons set forth above, Patentee therefore respectfully requests that the Director reverse the USPTO's Decision, grant a total patent term adjustment of 976 days to the '700 patent, and issue a decision on this petition that is consistent with the Federal Circuit's *Wyeth* decision and the USPTO's current policies.

If there are any fees due in connection with the filing of this request, please charge such fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: February 4, 2010

By: 

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent No.: 7,547,700	)	
	)	
Bernard Vacher et al.	)	Group Art Unit: 1625
	)	
Issued: June 16, 2009	)	Examiner: David K. O'Dell
	)	
Application No.: 10/518,394	)	Confirmation No.: 8214
	)	
For: NOVEL ARYL-[4-HALO-4	)	
(HETEROARYLMETHYLAMINO)-	)	
METHYL]-PIPERIDIN-1-YL]-	)	
METHANONE DERIVATIVES,	)	
METHODS FOR PRODUCTION AND	)	
USE THEREOF AS MEDICAMENTS	)	

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**APPLICATION FOR PATENT TERM ADJUSTMENT-POST GRANT**

In accordance with 37 C.F.R. § 1.705(b), and pursuant to the Federal District Court for the District of Columbia's decision in *Wyeth v. Dudas* on September 20, 2008, Applicant hereby requests reconsideration of the patent term adjustment under 35 U.S.C. § 154(b) for the above-identified patent. This application is being filed within two months of issuance of the above-identified patent on June 16, 2009, as required by 37 C.F.R. § 1.705(d).

**I. Statement of the Facts Involved**

**A. Correct Patent Term Adjustment**

According to the information printed on the face of the above-identified issued patent, this patent is entitled to 430 days of patent term adjustment.

Applicant has calculated a patent term adjustment of 977 days based on the following facts:

The Application was filed December 17, 2004.

The first Office Action on the merits was dated September 19, 2007, creating a U.S. Patent and Trademark Office (**PTO**) **delay of 579 days**.

A Response to the September 19, 2007 Office Action was filed February 19, 2008, creating an **Applicant delay of 62 days**.

A non-final Office Action was dated May 30, 2008.

A Response to the May 30, 2008 Office Action was filed November 25, 2008, creating an **Applicant delay of 87 days**.

The Application was allowed on February 9, 2009.

The issue fee was paid May 8, 2009.

The patent issued on June 16, 2009.

The three year pendency date for determination of patent term adjustment is December 17, 2007, creating an additional **PTO delay of 547 days**.

Thus, the total adjustment based on PTO delay is 1126 (579+547) days and the reduction in term adjustment is 149 (62+87) days, resulting in a patent term adjustment of 977 (1126-149) days. Applicant respectfully requests that the current patent term adjustment be reconsidered.

#### **B. Terminal Disclaimer**

The above-identified application is not subject to a Terminal Disclaimer.

**C. Reasonable Efforts**

There were no circumstances constituting a failure to engage in reasonable efforts to conclude processing of examination of the above-identified application, as set forth in 37 C.F.R. § 1.704.

**II. Fee**

As required by 37 C.F.R. § 1.705(b)(1), this application is accompanied by the required fee of \$200.00. Please charge any deficiencies to Deposit Account 06-0916. If there are any other fees due in connection with the filing of this request, please charge them to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: July 30, 2009

By: 

Laurence A. Shumway, Ph.D.  
Reg. No. 61,169  
617.452.1689

# United States Court of Appeals for the Federal Circuit

2009-1120

WYETH  
and ELAN PHARMA INTERNATIONAL LIMITED,

Plaintiffs-Appellees,

v.

David J. Kappos, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL  
PROPERTY and DIRECTOR OF THE UNITED STATES PATENT  
AND TRADEMARK OFFICE,

Defendant-Appellant.

Patricia A. Carson, Kaye Scholer LLP, of New York, New York, argued for plaintiffs-appellees. With her on the brief were Richard G. Greco; and David O. Bickart, of Washington, DC. Of counsel were Thomas E. Malone, Elan Pharmaceuticals, of South San Francisco, California; and Reem F. Jishi, Wyeth, of Madison, New Jersey.

Christine N. Kohl, Attorney, Appellate Staff, Civil Division, United States Department of Justice, of Washington, DC, argued for defendant-appellant. On the brief were Tony West, Assistant Attorney General, Channing D. Phillips, Acting United States Attorney, and Scott R. McIntosh and Abby C. Wright, Attorneys. Of counsel on the brief were James A. Toupin, General Counsel, and Raymond T. Chen, Deputy General Counsel and Solicitor, United States Patent and Trademark Office, of Arlington, Virginia.

William G. James, II, Kenyon & Kenyon LLP, of Washington, DC, for amicus curiae Hospira, Inc. With him on the brief was Richard W. Ward.

Jeffrey B. Elikan, Covington & Burling LLP, of Washington, DC, for amicus curiae Pharmaceutical Research and Manufacturers of America, et al. With him on the brief were E. Edward Bruce and James P. Sullivan.

Appealed from: United States District Court for the District of Columbia

Judge James Robertson

# United States Court of Appeals for the Federal Circuit

2009-1120

WYETH  
and ELAN PHARMA INTERNATIONAL LIMITED,

Plaintiffs-Appellees,

v.

David J. Kappos, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL  
PROPERTY and DIRECTOR OF THE UNITED STATES PATENT  
AND TRADEMARK OFFICE,

Defendant-Appellant.

Appeal from the United States District Court for the District of Columbia in case no. 07-CV-1492, Judge James Robertson.

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DECIDED: January 7, 2010

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Before RADER, PLAGER, and MOORE, Circuit Judges.

RADER, Circuit Judge.

I.

On summary judgment, the United States District Court for the District of Columbia held that plaintiffs Wyeth and Elan Pharma International Ltd. (collectively, “Wyeth”) were entitled to extended patent term adjustments under 35 U.S.C. § 154(b) due to the Patent and Trademark Office’s (the “PTO’s”) delay in prosecuting their patent applications. Because section 154(b) expressly permits this legal relief, this court affirms.

## II.

In 1994, the law changed the effective term of a patent from seventeen years commencing from issuance to twenty years from filing. See Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994). With the change came new ways of compensating patentees for PTO-caused delays during prosecution. Under the previous seventeen-year regime, PTO-caused delays could not affect patent terms because the term commenced upon issuance after any delays during patent acquisition. Under the twenty-year term, however, those delays consumed the effective term of a patent.

In 1999, the American Inventors Protection Act amended 35 U.S.C. § 154(b) to address this new problem. The new Act promised patent applicants a full patent term adjustment for any delay during prosecution caused by the PTO. This promise took the form of three distinct “guarantees” in 35 U.S.C. § 154(b)(1):

(A) Guarantee of prompt Patent and Trademark Office responses.--Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to [meet deadlines specified in clauses (i)-(iv)] . . .

the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

(B) Guarantee of no more than 3-year application pendency.--Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States . . .

the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

(C) Guarantee or adjustments for delays due to interferences, secrecy orders, and appeals.--Subject to the limitations under paragraph (2) . . . the term of the patent shall be extended 1 day for each day of the pendency of the proceeding, order, or review, as the case may be.

(emphases added). To summarize, paragraph A (the “A guarantee” or “A clause”) promises “prompt [PTO] responses” by extending the term of the patent one day for each day the PTO does not meet certain examination deadlines in subdivisions (i)-(iv). Id. § 154(b)(1)(A). One of these deadlines, for instance, requires a first response to a filed application within fourteen months. See id. § 154(b)(1)(A)(i). Paragraph B (the “B guarantee” or “B clause”) extends the term of the patent one day for each day issuance is delayed due to the PTO’s failure “to issue a patent within 3 years after the actual filing date of the application in the United States.” Id. § 154(b)(1)(B). Last, paragraph C allows for adjustments relating to delays resulting from interference proceedings, secrecy orders, and appeals. Id. § 154(b)(1)(C). At issue in this case are the A and B guarantees.

Both the A and B clauses are expressly subject to paragraph 2’s “In general” limitation:

In general. To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Id. § 154(b)(2)(A) (emphasis added). In other words, this limitation restricts the period of adjustment when any of the “periods of delay” “overlap.” This case asks this court to interpret and enforce the guarantees in the face of an “overlap” and “periods of delay” under section 154(b)(2)(A).

Section 154(b)(3) of the statute directs the PTO to “prescribe regulations establishing procedures for the application for and determination of patent term adjustments under this subsection.” Id. § 154(b)(3) (emphasis added). Under the guise

of that authority, the PTO promulgated 37 C.F.R. § 1.703(f) in 2000: “To the extent that periods of adjustment attributable to the [guarantees] overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.” (emphasis added). Other than adding the term “periods of adjustment,” this language repeated the text of section 154(b)(2)(A). The regulations later defined “periods of adjustment” as “the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed . . . .” 37 C.F.R. § 1.703(b) (2000). The regulation supplied no explanation about implementation or application of these rules.

In 2004, the PTO amended the regulation to replace “periods of adjustment” with “periods of delay.” 69 Fed. Reg. 21706 (2004). The PTO contended that this substitution clarified the regulation:

The language of former § 1.703(f) misled applicants into believing that [periods of A-delay] and [periods of B-delay] were overlapping only if the [period of A-delay] occurred more than three years after the actual filing date of the application. If an application is entitled to a [B-]adjustment . . . the entire period during which the application was pending before the [PTO] . . . , and not just the period beginning three years after the actual filing date of the application; is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A).

Id. (emphasis added). Thus, the “period of delay,” according to the PTO’s new definition, caused the B guarantee to start with the filing of the application, not three years later. Under that interpretation, “overlap” between A adjustments and B adjustments can arise and begin during the pendency of the patent application. For example, if a patent entitled to twenty days of A adjustments issues twenty days after the three year mark, then it is only entitled to a total of twenty days of adjustment. In



other words, the entire period of A delay “overlaps” with the entire period of B delay. Using this framework, the PTO uses either the greater of the A delay or B delay to determine the appropriate adjustment but never combines the two.

Wyeth and Elan Pharma are the owners of U.S. Patent Nos. 7,179,892 (the “’892 patent”) and 7,189,819 (the “’819 patent”)—inventions that treat Alzheimer’s disease. During the prosecution of each of their respective applications, the PTO undisputedly caused delays that gave the applicants entitlement to both A and B guarantees.

For the ’892 patent, the PTO calculated 610 days of A delay and 345 days of B delay. Of the 610 days of A delay, 51 occurred more than three years after the application was filed. During the prosecution, the applicant caused 148 days of delay. Thus, under section 154(b)(2)(C), any adjustment must be reduced by that amount. See 35 U.S.C. 154(b)(2)(C). Under its greater-of-A-or-B rubric, the PTO calculated the total adjustment at 462 days—i.e., 610 (the greater of A or B) - 148 (applicant delay). According to Wyeth, however, the “period of delay” for purposes of the B clause could not have started until three years after the application’s filing date. For that reason, the only possible “overlap” was any A delay occurring after the three-year mark. Because only 51 days of A delay occurred after the three year mark for the ’892 patent, the adjustment, according to Wyeth, should have been 756 days—i.e., 610 (A delay) + 345 (B delay) - 51 (“overlap”) - 148 (applicant delay).

For the ’819 patent, the PTO calculated 336 days of A delay and 827 days of B delay. Of the 336 days of A delay, 106 occurred after the three-year mark. In this case, the applicant caused 335 days of delay. The greater-of-A-or-B rubric yields an adjustment period of 492 days—i.e., 827 (the greater of A or B) - 335 (applicant delay).

Wyeth contends the adjustment period should have been 722 days—i.e., 336 (A delay) + 827 (B delay) - 106 (“overlap”) - 335 (applicant delay).

After filing petitions for reconsideration of the adjustments with the PTO, Wyeth filed the instant action in the District Court for the District of Columbia seeking an order directing the PTO to grant an adjustment per Wyeth’s interpretation. Both parties filed motions for summary judgment. Citing section 154(b)(3) as evidence of a delegation of authority to draft regulations, the PTO sought Chevron deference for its interpretation. See Chevron U.S.A., Inc. v. Natural Resources Def. Council, Inc., 467 U.S. 837 (1984).

The district court sided with Wyeth, finding first that the PTO “does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency.” Wyeth v. Dudas, 580 F. Supp. 2d 138, 141 (D.D.C. 2008) (citing Merck & Co. v. Kessler, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996)). The district court further found that even if Chevron was applicable, it would have rejected the PTO’s interpretation as contrary to the plain language of the statute. As the district court put it: “The problem with the PTO’s interpretation is that it considers the application delayed under [the B guarantee] during the period before it has been delayed.” Id. at 142 (emphasis in original).

### III.

This court reviews a grant of summary judgment without deference. Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1353 (Fed. Cir. 1998). Summary judgment is only appropriate if the court determines that there “is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c). Because both parties in the instant case perceive no genuine

issues of material fact, this court need only decide the question of law decided by the district court. “That question is one of statutory interpretation, one that an appellate court can independently determine without deference to the trial court’s interpretation.” Glaxo Operations UK Limited v. Quigg, 894 F.2d 392, 395 (Fed. Cir. 1990) (citing Madison Galleries, Ltd. v. United States, 870 F.2d 627, 629 (Fed. Cir. 1989)).

“As always, the ‘starting point in every case involving construction of a statute is the language itself.’” United States v. Hohri, 482 U.S. 64, 68 (1987) (quoting Kelly v. Robinson, 479 U.S. 36, 43 (1986)). When the terms of a statute are unambiguous, “judicial inquiry is complete, except ‘in rare and exceptional circumstances.’” Rubin v. United States, 449 U.S. 424, 430 (1981) (quoting TVA v. Hill, 437 U.S. 153, 187 n.33 (1978)). “Absent a clearly expressed legislative intention to the contrary, [the statute’s plain] language must ordinarily be regarded as conclusive.” Consumer Prod. Safety Comm’n v. GTE Sylvania, Inc., 447 U.S. 102, 108 (1980).

This court detects no ambiguity in the terms “periods of delay” and “overlap.” Each term has an evident meaning within the context of section 154(b). The limitation in section 154(b) only arises when “periods of delay” resulting from violations of the three guarantees “overlap.” 35 U.S.C. § 154(b)(2)(A). Significantly, the A and B guarantees expressly designate when and for what period they each respectively apply. Thus, this court can easily detect any overlap by examining the delay periods covered by the A and B guarantees.

A violation of the A guarantee—delays in meeting examination deadlines—begins with a “failure of the [PTO]” to meet one of the deadlines specified in subparagraphs (i)–(iv). Id. § 154(b)(1)(A). It ends when “the action described . . . is

taken.” Id. The “period of delay” for purposes of the A clause therefore runs from the date the PTO misses the specified deadline to the date (past the deadline) of response to the underlying action.

Correspondingly, a violation of the B guarantee—the one at the heart of the issue in this case—begins when the PTO fails “to issue a patent within 3 years after the actual filing date of the application in the United States . . . .” Id. § 154(b)(1)(B). It ends when “the patent is issued.” Id. The “period of delay” under the express language of the B clause therefore runs from the three-year mark after filing until the application issues.

Reading this framework into section 154(b)’s limitation provision makes it clear that no “overlap” happens unless the violations occur at the same time. Each “period of delay” has its own discrete time span whose boundaries are defined in section 154(b)(1). That is, each has a start and an end. Before the three-year mark, no “overlap” can transpire between the A delay and the B delay because the B delay has yet to begin or take any effect. If an A delay occurs on one day and a B delay occurs on a different day, those two days do not “overlap” under section 154(b)(2).

Under the PTO’s strained interpretation, B delay can occur anytime after the application is filed. To the contrary, the language of section 154(b) does not even permit B delay to start running until three years after the application is filed. The PTO’s position cannot be reconciled with the language of the statute. Thus, returning to the district court’s decision, this time with affirming approval: “The problem with the PTO’s interpretation is that it considers the application delayed under [the B guarantee] during the period before it has delayed.” Wyeth, 580 F. Supp. 2d at 142 (emphasis in original).

The PTO defends its interpretation by arguing that A delays during the first three years of prosecution ultimately lead to B delays after the three-year mark from filing. Put differently, it would be double counting if A and B delays were both used to adjust because A delays “cause” B delays. In that vein, the PTO highlights various scenarios where a hypothetical patentee appears to receive some type of windfall adjustment under the statute despite being in a similar position as other applicants who receive no similar adjustment. Indeed, the statute requires as much. Nonetheless, this court perceives potential perverse results as well under the PTO’s suggested interpretations. Under certain scenarios, both the PTO’s interpretation and the statute itself result in some imbalanced treatment of similarly-situated patentees.

For example, the language of section 154(b) presents a slight imbalance in the following hypothetical: suppose Applicant 1 receives a patent 3 years and 30 days after filing an application. In prosecuting the application, Applicant 1 incurred 30 days of A delay before the three-year mark. In the same hypothetical situation, suppose Applicant 2 also receives a patent 3 years and 30 days after filing an application but incurred no A delay during prosecution. Notably, both patents issued the same amount of time from filing—3 years and 30 days. Nonetheless, Applicant 1 would receive a 60 day adjustment whereas Applicant 2 would only receive a 30 day adjustment meaning Applicant 1’s effective term would be 30 days longer than Applicant 2.

By the same token, under the PTO’s counter-statutory interpretation, suppose Applicant 1 incurs 400 days of A delay before the three-year mark with the application issuing exactly three years after filing. Suppose Applicant 2 also incurs 400 days of A delay before the three-year mark, but in addition incurs a one-year delay by the PTO

after the three-year mark. Despite the fact each applicant incurred the same A delay, under the PTO's interpretation, Applicant 1's effective term would be a full year greater than Applicant 2's effective term. Simply put, the additional B delay incurred by Applicant 2 produces a shorter effective term.

Regardless of the potential of the statute to produce slightly different consequences for applicants in similar situations, this court does not take upon itself the role of correcting all statutory inequities, even if it could. In the end, the law has put a policy in effect that this court must enforce, not criticize or correct. See Harbison v. Bell, 129 S. Ct. 1481, 1493-94 (2009) (Thomas, J., concurring) (quoting Eldred v. Ashcroft, 537 U.S. 186, 222 (2003) ("Even if the proper interpretation of a statute upholds a 'very bad policy,' it 'is not within our province to second-guess' the 'wisdom of Congress' action' by picking and choosing our preferred interpretation from among a range of potentially plausible, but likely inaccurate, interpretations of a statute.")).

The PTO also passingly refers to the second clause of section 154(b)(2)(A) for support: "the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A). While the PTO's argument on this point is unclear, that language does not provide any support for its interpretation. Significantly, the second clause of section 154(b)(2)(A) only takes effect upon satisfaction of the first clause. See id. § 154(b)(2)(A) ("To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap . . .") (emphasis added). Viewed in this light, a "delay" must refer consistently to the violation of either the A or B guarantees. "[T]he actual number

of days the issuance of the patent was delayed” therefore refers to each day covered by a “period of delay” in the first clause with no such day counted twice.

This court has also examined the legislative history of the 1999 Act but finds nothing to rescue the PTO’s cause. In the first place, only a “most extraordinary showing of contrary intentions” by Congress justifies a departure from the plain language of a statute. Garcia v. United States, 469 U.S. 70, 75 (1984). Far from intentions contrary to the meaning of section 154(b), the legislative history generally supports the interpretation required by the statutory language itself. The AIPA’s section-by-section analysis states:

Accordingly, subtitle D removes the 10-year caps from the existing provisions, adds a new provision to compensate applicants fully for USPTO-caused administrative delays, and, for good measure, includes a new provision guaranteeing diligent applicants at least a 17-year term by extending the term of any patent not granted within three years of filing. Thus, no patent applicant diligently seeking to obtain a patent will receive a term of less than the 17 years as provided under the pre-GATT standard; in fact, most will receive considerably more.

H.R. Rep. No. 106-464, at 125 (1994) (emphases added). From this, it is apparent that the statutory language should provide a minimum seventeen-year term for most patents. The outcome suggested by the language itself effectuates this goal by ensuring such a minimum term unless the applicant caused delays.

The PTO urges this court to read that passage in view of the 25-month average patent pendency at that time—that is, most patents received more than a seventeen-year term because of the shorter prosecution periods. Even taking that context into account, this court notes that the PTO’s interpretation effectively creates a seventeen-year term cap where B delays are greater than A delays. In other words, any A delay before the three-year mark causes PTO delays in issuance beyond the three-year

mark—thereby violating the B guarantee. Together, these effects, under the PTO's desire to aggregate A and B delays, reduce the effective term of the patent towards seventeen years. The passage from the House report does not expressly preclude that type of effective cap, but the context suggests a very different goal of supplying adequate protection that will often be “considerably more” than the PTO's effective cap. In any event, the House report does not produce any “extraordinary showing of contrary intentions.” Moreover, if the Act intended to create a seventeen-year cap, it could have easily done so with just a few words.

The PTO next highlights the belated addition of the B guarantee into section 154(b) for support. Before enactment of AIPA, section 154(b) only provided extensions for the category that now fall under C adjustments. See 35 U.S.C. § 154(b)(1)-(2) (1996). The earlier versions of AIPA added only A delays. See S. 507, 105th Cong., 143 Cong. Rec. S2678, S2696-97 (Mar. 20, 1997). Not long afterwards, B adjustments appeared in drafts of section 154(b). See H.R. 400, 105th Cong., 143 Cong. Rec. H1629, H1651 (April 17, 1997). According to the PTO, this legislative history suggests that Congress did not intend to give patentees already eligible for A adjustments additional compensation where the A delay occurred during the first three years of prosecution. Even if these ambiguous timing observations suggested some kind of substantive difference in the meaning of section 154(b), they would be wholly irrelevant to interpretation of the law itself. Such opaque timing observations hardly amount to a “most extraordinary showing of contrary intentions,” especially when the language of the statute trumpets its meaning by itself. See Harbison, 129 S. Ct. at 1494 (Thomas, J., concurring) (“And Congress’ silence certainly does not empower us to go even farther



and incorporate such an assumption into the text of these provisions.”). In sum, legislative history—always a very dull instrument for extracting the essence of statutory meaning—provides no reason to depart from the language of section 154(b).

Last, the PTO contends that its interpretation is entitled to deference under either Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984) or Skidmore v. Swift & Co., 323 U.S. 134 (1944). Because the language of the statute itself controls this case and sets an unambiguous rule for overlapping extensions, this court detects no reason to afford special deference to the PTO’s interpretation. See Smith v. City of Jackson, Miss., 544 U.S. 228, 267 (2005) (quoting Pub. Employees Ret. Sys. of Ohio v. Betts, 492 U.S. 158, 171 (1989)) (“Of course, it is elementary that ‘no deference is due to agency interpretations at odds with the plain language of the statute itself.’”).

#### IV.

This court therefore affirms the judgment of the district court. Section 154(b)’s language is clear, unambiguous, and intolerant of the PTO’s suggested interpretation. For that reason, this court accords no deference to the PTO’s greater-of-A-or-B rubric.

AFFIRMED



UNITED STATES PATENT AND TRADEMARK OFFICE

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**OFFICE OF PETITIONS**

In re Patent No. 7,547,700 :  
Issued: June 16, 2009 :  
Application No. 10/518,394 : PATENT TERM ADJUSTMENT  
Filed: December 17, 2004 :  
Dkt. No.: 03715.0144 :

This is a decision on the "APPLICATION FOR PATENT TERM ADJUSTMENT-OST GRANT," filed July 30, 2009. This matter is being properly treated under 37 CFR 1.705(d).

Patentees request correction of the patent term adjustment from 430 days to 977 days. Patentees request this correction on the sole basis that the Office took in excess of three years to issue the above-referenced patent.

The application for patent term adjustment (PTA) under 37 CFR 1.705(d) is **DISMISSED**.

The above-identified application matured into U.S. Pat. No. 7,547,700 on June 16, 2009. The patent issued with a patent term adjustment of 430 days. The instant application of patent term adjustment is timely filed pursuant to 37 CFR 1.705(d). Patentees argue that in view of Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008), the patent is entitled to an adjustment of 977 days (579 days pursuant to 35 USC 154(b)(1)(A) *plus* 547 days pursuant to 35 USC 154(b)(1)(B) *less* 149 days applicant delay).

Under 37 CFR 1.703(f), patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR 1.702 reduced by the period of time equal to the period of time during which patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704. In other words, patentees are entitled to the period of Office delay reduced by the period of applicant delay.

The Office asserts that as of the issuance of the patent on June 16, 2009, the application was pending three years and 546 days after national stage commenced under 35 U.S.C. 371(b) or (f) in an international application (December 19, 2007 to June 16, 2009). The Office agrees that certain action was not taken within the specified time frame, and thus, the application was pending 14 months and 579 days prior to the mailing of the non-final Office action on September 19, 2007. At issue is whether patentees should accrue 546 days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as 579 days for Office failure to take a certain action within a specified time frame (or examination delay).

The Office contends that the period of 546 days of delay in issuance of the patent under 37 CFR 1.702(b) overlaps with the period of 579 days of examination delay under 37 CFR 1.702(a). Patentees' calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

To the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in *Explanation of 37 CFR 1.703(f)*<sup>1</sup> and of the *United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See *Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule*, 65 Fed. Reg. 54366 (Sept. 18, 2000). See also *Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule*, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004).

Further, as stated in the *Explanation of 37 CFR 1.703(f)* and of the *United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant

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<sup>1</sup> Likewise, 37 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in §1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay “overlap” under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding §1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay “overlap” under 35 U.S.C. 154(b)(2)(A) is the period during which the application was pending before the Office beginning on the date that national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, December 18, 2004, and ending on the date that the patent issued, June 16, 2009.

Pursuant to 35 U.S.C. 154(b)(1)(A) and 37 CFR 1.702(a)(1), the application was pending 14 months and 579 days prior to the issuance of the non-final Office action on September 19, 2007. Pursuant to 35 U.S.C. 154(b)(1)(B) and 37 CFR 1.702(b), the application was pending three years and 546 days prior to the issuance of the patent on June 16, 2009.

The 546 days of delay in issuance of the patent under 37 CFR 1.702(b) overlap with the 579 days of patent term adjustment under 37 CFR 1.702(a). Entry of both the 546 days and the 579 days is neither permitted nor warranted given that 579 days is the actual number of days issuance of the patent was delayed.

Accordingly, at issuance, having considered the 546 days of Office delay under the three-year pendency provision in conjunction with the 579 days of examination delay, reduced 149 days for applicant delay, the Office properly entered 430 days of patent term adjustment.

In view thereof, no adjustment to the patent term will be made.

No additional fees are due in connection with this matter.

Telephone inquiries specific to this matter should be directed to the undersigned at (571) 272-3205.



Alesia M. Brown  
Petitions Attorney  
Office of Petitions

**DEPARTMENT OF COMMERCE**

**United States Patent and Trademark Office**

**[Docket No.: PTO-P-2010-0006]**

**Interim Procedure for Patentees to Request a Recalculation of the Patent Term  
Adjustment to Comply with the Federal Circuit Decision in Wyeth v. Kappos  
Regarding the Overlapping Delay Provision of 35 U.S.C. 154(b)(2)(A)**

**AGENCY:** United States Patent and Trademark Office, Commerce.

**ACTION:** Notice.

**SUMMARY:** The United States Patent and Trademark Office (USPTO) is modifying the computer program it uses to calculate patent term adjustments in light of Wyeth v. Kappos, No. 2009-1120 (Fed. Cir., Jan. 7, 2010). The USPTO expects to complete this software modification by March 2, 2010. In the meantime, the USPTO is providing patentees with the ability to request a recalculation of their patent term adjustment without a fee as an alternative to the petition and fee required by 37 CFR 1.705(d). In order to qualify, a form requesting a recalculation of the patent term adjustment must be submitted no later than 180 days after the patent has issued and the patent must be issued

prior to March 2, 2010. In addition, this procedure is only available for alleged errors that are specifically identified in Wyeth. The USPTO is deciding pending petitions under 37 CFR 1.705 in accordance with the Wyeth decision. This notice also provides information concerning the Patent Application Information Retrieval (PAIR) screen that displays the patent term adjustment calculation.

**DATES: EFFECTIVE DATE:** The procedure set forth in this notice is effective on [Insert date of publication in the FEDERAL REGISTER].

**APPLICABILITY DATE:** The procedure set forth in this notice is applicable only to patents issued prior to March 2, 2010, in which a request for recalculation of patent term adjustment in view of Wyeth is filed within 180 days of the day the patent was granted.

**FOR FURTHER INFORMATION CONTACT:** The Office of Patent Legal Administration by telephone at (571) 272-7702, or by mail addressed to: Mail Stop Comments-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

**SUPPLEMENTARY INFORMATION:** Under 35 U.S.C. 154(b)(1), an applicant is entitled (subject to certain conditions and limitations) to patent term adjustment for the following reason: (1) if the USPTO fails to take certain actions during the examination and issue process within specified time frames (35 U.S.C. 154(b)(1)(A)), which are known as the "A" delays; (2) if the USPTO fails to issue a patent within three years of the

actual filing date of the application (35 U.S.C. 154(b)(1)(B)), which are known as the “B” delays; and (3) for delays due to interference, secrecy order, or successful appellate review (35 U.S.C. 154(b)(1)(C)), which are known as the “C” delays. 35 U.S.C. 154(b)(2)(A) provides that “[t]o the extent that periods of delay attributable to grounds specified in [35 U.S.C. 154(b)(1)] overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” The USPTO interpreted this provision as covering situations in which a delay by the USPTO contributes to multiple bases for adjustment (the “pre-Wyeth” interpretation of 35 U.S.C. 154(b)(2)(A)). See Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 FR 34283 (June 21, 2004). The United States Court of Appeals for the Federal Circuit, however, recently held in Wyeth that the USPTO’s interpretation of 35 U.S.C. 154(b)(2)(A) was too strict, and that periods of delay overlap under 35 U.S.C. 154(b)(2)(A) only if the periods which measure the amount of adjustment under 35 U.S.C. 154(b)(1) occur on the same calendar day.

The USPTO makes patent term adjustment determinations by a computer program that uses the information recorded in the USPTO’s Patent Application Locating and Monitoring (PALM) system, except when an applicant requests reconsideration pursuant to 37 CFR 1.705. See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 FR 56365, 56370, 56380-81 (Sept. 18, 2000) (final rule). The USPTO is in the process of revising the computer program it uses to calculate patent term adjustment to calculate overlapping delays consistent with the Federal Circuit’s

interpretation of 35 U.S.C. 154(b)(2)(A) in Wyeth. The USPTO expects the revisions to the patent term adjustment computer program to be in place for use on the patents issuing on March 2, 2010.

Patentees should note that the patent term adjustment provisions of 35 U.S.C. 154(b) are complex, there are numerous types of communications that are exchanged between applicants and the USPTO during the patent application process, the PALM system was not originally designed for the purpose of calculating patent term adjustment as provided in 35 U.S.C. 154(b), and one or more of the time frames specified in of 35 U.S.C. 154(b)(1)(A) and (B) are not met presently in a high percentage of the patents. In addition, revisions to the patent term adjustment computer program necessary to calculate overlapping delays consistent with the Federal Circuit's interpretation of 35 U.S.C. 154(b)(2)(A) in Wyeth significantly increases the complexity of the patent term adjustment computer program. Thus, for patents issuing on or after March 2, 2010, a patentee who believes that the patent term adjustment calculation for his or her patent is not correct must file a request for reconsideration under 37 CFR 1.705(d) that complies with the requirements of 37 CFR 1.705(b)(1) and (b)(2) within two months of the date the patent issued. The USPTO is modifying and will continue to modify the patent term adjustment computer program as it becomes aware of situations in the patent term adjustment computer program where it is not correctly calculating the applicable patent term adjustment.



Requests for Reconsideration of the Patent Term Adjustment indicated in the Patent:

37 CFR 1.705(d) provides, in part, that any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and must comply with the requirements of 37 CFR 1.705(b)(1) and (b)(2).

35 U.S.C. 154(b)(4) provides that an applicant dissatisfied with a determination made by the Director under 35 U.S.C. 154(b)(3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent.

The USPTO is providing an optional procedure under which patentees seeking a revised patent term adjustment in a patent issued prior to March 2, 2010, may request that the USPTO recalculate the patent term adjustment without a request for reconsideration under 37 CFR 1.705(d) (or fee), provided that the patentee's sole basis for requesting reconsideration of the patent term adjustment in the patent is the USPTO's pre-Wyeth interpretation of 35 U.S.C. 154(b)(2)(A) and such a request is filed within 180 days of the day the patent was granted. The USPTO is providing a Request for Recalculation of Patent Term Adjustment in View of Wyeth form (PTO/SB/131) for use in making such a request. The Request for Recalculation of Patent Term Adjustment in View of Wyeth form (PTO/SB/131) is available on the USPTO Web site at <http://www.uspto.gov/forms/index.jsp>. This procedure and Request for Recalculation of Patent Term Adjustment in View of Wyeth form (PTO/SB/131) are applicable only for patents that issue prior to March 2, 2010. The USPTO will deny as untimely any request for recalculation of patent term adjustment indicated on a patent that is **not** filed within

180 days of the day the patent was granted. Patentees are reminded that this is an optional procedure, and that any patentee who wishes to preserve his or her right to review in the United States District Court for the District of Columbia of the USPTO's patent term adjustment determination must ensure that he or she also takes the steps required under 35 U.S.C. 154(b)(3) and (b)(4) and 37 CFR 1.705 in a timely manner.

The fee specified in 37 CFR 1.18(e) is required for a request for reconsideration under 37 CFR 1.705 (37 CFR 1.705(b)(1)), and the USPTO may only refund fees paid by mistake or in excess of that required (35 U.S.C. § 42(d)). Therefore, the procedure set forth in this notice is **not** a basis for requesting a refund of the fee specified in 37 CFR 1.18(e) for any request for reconsideration under 37 CFR 1.705, including any previously filed request that was solely based on the USPTO's pre-Wyeth interpretation of 35 U.S.C. 154(b)(2)(A).

The procedure set forth in this notice and the Request for Recalculation of Patent Term Adjustment in View of Wyeth form (PTO/SB/131) may not be used to request a reconsideration of the patent term adjustment indicated in the notice of allowance in an application that has not yet issued as a patent. If the application issues as a patent prior to March 2, 2010, the optional procedure set forth in this notice and the Request for Recalculation of Patent Term Adjustment in View of Wyeth form (PTO/SB/131) may be used to request recalculation of the patent term adjustment provided on the patent. It is expected that for applications issuing as patents on or after March 2, 2010, the patent

term adjustment calculation will be consistent with the Federal Circuit's interpretation of 35 U.S.C. 154(b)(2)(A) in Wyeth.

The USPTO is deciding any currently pending request for reconsideration of the patent term adjustment indicated in the patent under 37 CFR 1.705(d) that was filed within two months of the date the patent issued consistent with the Federal Circuit's interpretation of 35 U.S.C. 154(b)(2)(A) in Wyeth. Patentees who received a decision on a request for reconsideration of the patent term adjustment indicated in the patent under 37 CFR 1.705(d) under the USPTO's pre-Wyeth interpretation of 35 U.S.C. 154(b)(2)(A) may file a request for reconsideration of that decision if such a request for reconsideration is filed within two months of the date of the decision on a request for reconsideration (37 CFR 1.181(f)). If the patentee's sole basis for requesting reconsideration of the decision is the USPTO's pre-Wyeth interpretation of 35 U.S.C. 154(b)(2)(A), the request for reconsideration need only state that reconsideration is being requested in view of the Federal Circuit's decision in Wyeth (the Request for Recalculation of Patent Term Adjustment in View of Wyeth form (PTO/SB/131) may also be used for this purpose).

Patentees seeking a revised patent term adjustment in a patent issued on or after March 2, 2010, must file a request for reconsideration under 37 CFR 1.705(d) that complies with the requirements of 37 CFR 1.705(b)(1) and (b)(2) within two months of the date the patent issued.

To the extent that the procedures adopted under the authority of 35 U.S.C. 2(b)(2) and 154(b)(3) require that any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and include the information required by 37 CFR 1.705(b)(2) and the fee required by 37 CFR 1.18(e), these requirements are hereby sua sponte waived for patents that meet all of the following criteria: (1) the patent must be issued prior to March 2, 2010; (2) the patentee's sole basis for requesting reconsideration of the patent term adjustment in the patent is the USPTO's pre-Wyeth interpretation of 35 U.S.C. 154(b)(2)(A); and (3) the Request for Recalculation of the Patent Term Adjustment in View of Wyeth form (PTO/SB/131) is filed within 180 days of the day the patent was granted. See 37 CFR 1.183. This waiver does not apply to patents issued on or after March 2, 2010, to requests that the USPTO recalculate the patent term adjustment for alleged errors other than that identified in Wyeth, or to any request for reconsideration of the patent term adjustment indicated in the patent filed later than 180 days after the patent was granted.

**Paperwork Reduction Act:** This notice involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The collection of information involved in this notice is covered by OMB control number 0651-0020.

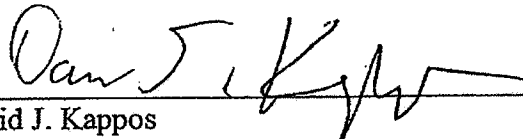
Patent Term Adjustment Information Displayed in PAIR: The USPTO provides a patent term adjustment calculation screen that is viewable through PAIR. The patent term adjustment screen has been displaying the following information at the right hand

column: (1) USPTO delay days (the number of days of "A" and "C" delay); (2) Three Year Delay days (the number of days of "B" delay); (3) Applicant Delay days (the number of days by which the USPTO delay days will be reduced); and (4) the Total Patent Term Adjustment. Patentees who use the PAIR patent term adjustment calculation screen should note that it does not display the periods of delay which overlap and thus is not adequate for calculating the patent term under the Federal Circuit's interpretation of 35 U.S.C. 154(b)(2)(A) in Wyeth. The USPTO plans to revise this screen to show: (1) the number of days of "A" delay; (2) the number of days of "B" delay; (3) the number of days of "C" delay; (4) the number of days of "A" delay that overlap with a day of "B" delay plus the number of days of "A" delay that overlap with a day of "C" delay (the provisions of 35 U.S.C. 154(b)(1)(B)(ii) prevent a "B" delay period and "C" delay period from overlapping); (5) the number of days of non-overlapping USPTO delay; (6) the number of days of applicant delay; and (7) the total patent term adjustment. The revised PAIR patent term adjustment screen, however, will not be ready by March 2, 2010. The USPTO expects the revised PAIR patent term adjustment screen to be ready by July of 2010.

**Nothing in this notice shall be construed as a waiver of the requirement of 35 U.S.C. 154(b)(4) that any civil action by an applicant dissatisfied with a determination made by the Director under 35 U.S.C. 154(b)(3) be filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent.**

Date:

1/26/10

  
\_\_\_\_\_  
David J. Kappos  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office